



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,344	02/09/2004	Toshiharu Ohta	248475US0CIP	9585
22850	7590	09/28/2006	EXAMINER	
C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			ROBINSON, BINTA M	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/773,344	Applicant(s) OHTA ET AL.	
	Examiner Thomas McKenzie, Ph.D.	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an application filed on 2/9/04. There are fifty-nine claims pending. Claims 1-40 are compound claims. Claims 41-51 appear to be composition claims. Claims 52 and 53 are method of using claims. Claims 54-59 are claims to chemical intermediates. The application concerns some cyclic bis-amido compounds, compositions, and uses thereof.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims parts of 1-11, 28-31, and 35-40, drawn to 1,2-disubstituted-cyclopropane compounds of the formula (1) with Q^3 = cyclopropyl and Q^5 = CH_2 , classified in class 564, subclass 157, among others.
- II. Claims parts of 1-11, 28-31, and 35-40, drawn to 1,2-disubstituted cyclobutane compounds of the formula (1) with Q^3 = cyclobutyl and Q^5 = CH_2-CH_2 , classified in class 564, subclass 157, among others.
- III. Claims parts of 1-15, 28-32, and 35-40, drawn to 1,2-disubstituted-cyclopentane compounds of the formula (1) with Q^3 = cyclopentyl and Q^5 = $CH_2-CH_2-CH_2$, classified in class 564, subclass 157, among others.

- IV. Claims 15, 16, 33, and 34 and parts of 1-14, 28-31, and 35-40, drawn to 1,2-disubstituted-cyclohexane compounds of the formula (1) with Q^3 = cyclohexyl and Q^5 = $\text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.
- V. Claims parts of 1-14, 28-32, and 35-40, drawn to 1,2-disubstituted-cycloheptane compounds of the formula (1) with Q^3 = cycloheptyl and Q^5 = $\text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.
- VI. Claims parts of 1-14, 28-32, and 35-40, drawn to 1,2-disubstituted-cyclooctane compounds of the formula (1) with Q^3 = cyclooctyl and Q^5 = $\text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.
- VII. Claims parts of 1-11, 28-31, and 35-40, drawn to 1,2-disubstituted-cyclononane compounds of the formula (1) with Q^3 = cyclononyl and Q^5 = $\text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.
- VIII. Claims parts of 1-11, 28-31, and 35-40, drawn to 1,2-disubstituted-cyclodecane compounds of the formula (1) with Q^3 = cyclodecyl and

$Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

- IX. Claims parts of 1-13, 17-32, and 35-40, drawn to 3,4-disubstituted-perhydropyran compounds of the formula (1) with $Q^3 =$ perhydropyranyl and $Q^5 = (\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 0$, $n = 1$, A = oxygen, classified in class 549, subclass 424, among others.
- X. Claims parts of 1-13, 17-32, and 35-40, drawn to 3,4-disubstituted-piperidine compounds of the formula (1) with $Q^3 =$ piperidiny1 and $Q^5 = (\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 0$, $n = 1$, A = a nitrogen atom or NH, classified in class 546, subclass 234, among others.
- XI. Claims parts of 1-13, 17-32, and 35-40, drawn to 3,4-disubstituted-piperidine compounds of the formula (1) with $Q^3 =$ piperidiny1 and $Q^5 = (\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 1$, $n = 0$, A = a nitrogen or NH, classified in class 546, subclass 234, among others.
- XII. Claims parts of 1-13, 17-32, and 35-40, drawn to 3,4-disubstituted-pyrrolidine compounds of the formula (1) with $Q^3 =$ pyrrolidiny1 and $Q^5 = (\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 0$, $n = 0$, A = a nitrogen atom or NH, classified in class 548, subclass 557, among others.

- XIII. Claims parts of 1-13, 17-32, and 35-40, drawn to 3,4-disubstituted-perhydrothiopyran compounds of the formula (1) with $Q^3 =$ perhydrothiopyranyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = S, SO, \text{ or } SO_2$, classified in class 549, subclass 28, among others.
- XIV. Claims parts of 1-13, 17-32, and 35-40, drawn to 4,5-disubstituted-perhydro-1,2-oxazine compounds of the formula (1) with $Q^3 =$ perhydro-1,2,oxazinyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = -O-NH$, classified in class 544, subclass 63, among others.
- XV. Claims parts of 1-13, 17-32, and 35-40, drawn to 4,5-disubstituted-perhydropyridazine compounds of the formula (1) with $Q^3 =$ perhydropyridazinyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = NH-NH$, classified in class 544, subclass 224, among others.
- XVI. Claims parts of 1-13, 17-32, and 35-40, drawn to 4,5-disubstituted-perhydro-1,2-thiazine compounds of the formula (1) with $Q^3 =$ perhydro-1,2-thiazinyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = S-NH, SO-NH, \text{ or } SO_2-NH$, classified in class 544, subclass 3, among others.

XVII. Claims parts of 1-13, 17-32, and 35-40, drawn to all other compounds of formula (1) with $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, and all values of m, n, and A not described above, classified in class 540, subclass 450, among others.

XVIII-XXXIV. Claims parts of 41-51, drawn to compositions made from compounds of the 17 distinct cores listed above, classified in class 514, subclass 183, among others.

XXXV-CCVI. Claims parts of 52 and 53, drawn to treatment of any one disease of the 16 distinct diseases listed in the two claims by any one of the 17 groups of compounds listed above, classified in class 514, subclass 183, among others.

CCVII. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclopropane compounds of the formula (4) with $Q^3 = \text{cyclopropyl}$ and $Q^5 = CH_2$, classified in class 564, subclass 157, among others.

CCVIII. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclobutane compounds of the formula (4) with $Q^3 = \text{cyclobutyl}$ and $Q^5 = CH_2-CH_2$, classified in class 564, subclass 157, among others.

CCIX. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclopentane compounds of the formula (4) with $Q^3 = \text{cyclopentyl}$ and

$Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCX. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclohexane compounds of the formula (4) with $Q^3 = \text{cyclohexyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXI. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cycloheptane compounds of the formula (4) with $Q^3 = \text{cycloheptyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXII. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclooctane compounds of the formula (4) with $Q^3 = \text{cyclooctyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXIII. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclononane compounds of the formula (4) with $Q^3 = \text{cyclononyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

- CCXIV. Claims parts of 54, 56, and 58, drawn to 1,2-disubstituted-cyclodecane compounds of the formula (4) with Q^3 = cyclodecyl and Q^5 = $\text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.
- CCXV. Claims parts of 54, 56, and 58, drawn to 3,4-disubstituted-perhydropyran compounds of the formula (4) with Q^3 = perhydropyranyl and Q^5 = $(\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 0$, $n = 1$, A = oxygen, classified in class 549, subclass 424, among others.
- CCXVI. Claims parts of 54, 56, and 58, drawn to 3,4-disubstituted-piperidine compounds of the formula (4) with Q^3 = piperidinyl and Q^5 = $(\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 0$, $n = 1$, A = a nitrogen atom or NH, classified in class 546, subclass 234, among others.
- CCXVII. Claims parts of 54, 56, and 58, drawn to 3,4-disubstituted-piperidine compounds of the formula (4) with Q^3 = piperidinyl and Q^5 = $(\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, $m = 1$, $n = 0$, A = a nitrogen or NH, classified in class 546, subclass 234, among others.
- CCXVIII. Claims parts of 54, 56, and 58, drawn to 3,4-disubstituted-pyrrolidine compounds of the formula (4) with Q^3 = pyrrolidinyl and

$Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 0$, $A =$ a nitrogen atom or NH, classified in class 548, subclass 557, among others.

CCXIX. Claims parts of 54, 56, and 58, drawn to 3,4-disubstituted-perhydrothiopyran compounds of the formula (4) with $Q^3 =$ perhydrothiopyranyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = S$, SO , or SO_2 , classified in class 549, subclass 28, among others.

CCXX. Claims parts of 54, 56, and 58, drawn to 4,5-disubstituted-perhydro-1,2-oxazine compounds of the formula (4) with $Q^3 =$ perhydro-1,2,oxazinyll and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = -O-NH$, classified in class 544, subclass 63, among others.

CCXXI. Claims parts of 54, 56, and 58, drawn to 4,5-disubstituted-perhydropyridazine compounds of the formula (4) with $Q^3 =$ perhydropyridazinyll and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, $A = NH-NH$, classified in class 544, subclass 224, among others.

CCXXII. Claims parts of 54, 56, and 58, drawn to 4,5-disubstituted-perhydro-1,2-thiazine compounds of the formula (4) with $Q^3 =$ perhydro-1,2-thiazinyll and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$,

$n = 1$, $A = \text{S-NH}$, SO-NH , or $\text{SO}_2\text{-NH}$, classified in class 544, subclass 3, among others.

CCXXIII. Claims parts of 54, 56, and 58, drawn to all other compounds of formula (4) with $Q^5 = (\text{CH}_2)_m\text{-CH}_2\text{-A-CH}_2\text{-(CH}_2)_n\text{-}$, and all values of m , n , and A not described above, classified in class 540, subclass 450, among others.

CCXXIV. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclopropane compounds of the formula (9) with $Q^3 = \text{cyclopropyl}$ and $Q^5 = \text{CH}_2$, classified in class 564, subclass 157, among others.

CCXXV. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclobutane compounds of the formula (9) with $Q^3 = \text{cyclobutyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXVI. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclopentane compounds of the formula (9) with $Q^3 = \text{cyclopentyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXVII. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclohexane compounds of the formula (9) with $Q^3 = \text{cyclohexyl}$ and

$Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXVIII. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cycloheptane compounds of the formula (9) with $Q^3 = \text{cycloheptanyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXIX. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclooctane compounds of the formula (9) with $Q^3 = \text{cyclooctyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXX. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclononane compounds of the formula (9) with $Q^3 = \text{cyclononyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXXI. Claims parts of 55, 57, and 59, drawn to 1,2-disubstituted-cyclodecane compounds of the formula (9) with $Q^3 = \text{cyclodecyl}$ and $Q^5 = \text{CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2\text{-CH}_2$, classified in class 564, subclass 157, among others.

CCXXXII Claims parts of 55, 57, and 59, drawn to 3,4-disubstituted-

perhydropyran compounds of the formula (9) with $Q^3 =$

perhydropyranyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$,

A = oxygen, classified in class 549, subclass 424, among others.

CCXXXIII. Claims parts of 55, 57, and 59, drawn to 3,4-disubstituted-

piperidine compounds of the formula (9) with $Q^3 =$ piperidinyl and Q^5

$= (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 1$, A = a nitrogen atom or

NH, classified in class 546, subclass 234, among others.

CCXXXIV. Claims parts of 55, 57, and 59, drawn to 3,4-disubstituted-

piperidine compounds of the formula (9) with $Q^3 =$ piperidinyl and Q^5

$= (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 1$, $n = 0$, A = a nitrogen or NH,

classified in class 546, subclass 234, among others.

CCXXXV. Claims parts of 55, 57, and 59, drawn to 3,4-disubstituted-

pyrrolidine compounds of the formula (9) with $Q^3 =$ pyrrolidinyl and

$Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, $n = 0$, A = a nitrogen atom

or NH, classified in class 548, subclass 557, among others.

CCXXXVI. Claims parts of 55, 57, and 59, drawn to 3,4-disubstituted-

perhydrothiopyran compounds of the formula (9) with $Q^3 =$

perhydrothiopyranyl and $Q^5 = (CH_2)_m-CH_2-A-CH_2-(CH_2)_n-$, $m = 0$, n

= 1, A = S, SO, or SO₂, classified in class 549, subclass 28, among others.

CCXXXVII. Claims parts of 55, 57, and 59, drawn to 4,5-disubstituted-perhydro-1,2-oxazine compounds of the formula (9) with Q³ = perhydro-1,2,oxazinyl and Q⁵ = (CH₂)_m-CH₂-A-CH₂-(CH₂)_n-, m = 0, n = 1, A = -O-NH, classified in class 544, subclass 63, among others.

CCXXXVIII. Claims parts of 55, 57, and 59, drawn to 4,5-disubstituted-perhydropyridazine compounds of the formula (9) with Q³ = perhydropyridazinyl and Q⁵ = (CH₂)_m-CH₂-A-CH₂-(CH₂)_n-, m = 0, n = 1, A = NH-NH, classified in class 544, subclass 224, among others.

CCXXXIX. Claims parts of 55, 57, and 59, drawn to 4,5-disubstituted-perhydro-1,2-thiazine compounds of the formula (9) with Q³ = perhydro-1,2-thiazinyl and Q⁵ = (CH₂)_m-CH₂-A-CH₂-(CH₂)_n-, m = 0, n = 1, A = S-NH, SO-NH, or SO₂-NH, classified in class 544, subclass 3, among others.

CCXL. Claims parts of 55, 57, and 59, drawn to all other compounds of formula (9) with Q⁵ = (CH₂)_m-CH₂-A-CH₂-(CH₂)_n-, and all values of

m, n, and A not described above, classified in class 540, subclass 450, among others.

3. The inventions are distinct, each from the other because of the following reasons: inventions I-XVII, XVIII-XXXIV, CCVII-CCXXIII, and CCXXV-CCXL are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, for inventions as claimed the heterocyclic core of the structure given in claim 1 is the ring Q³. This ring is a mandatory feature and ranges in size from three to eleven atoms with multiple possible heteroatoms. These multiple claimed rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I, IX, X, and XII-XVII, XVIII, XXVIII, XXVI, and XXVII, and XXIX-XXXIV, and CCVII, CCXV, CCXVI, and CCIX-CCXXIII, and CCXXIV, CCXXXII, CCXXXIII, and CCXXXV-CCXL have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups IX, X, and XII-XVII. The basic names of these cyclic compounds differ,

thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Although Groups I-VIII and XVIII- XXV are classified together these are patently distinct rings, *i.e.* a reference on a cyclopropane would not be a reference against a claim to a cyclodecane. In addition, the different chemical names make the search for these separate cores burdensome to the Examiner.

Although groups X and XI, XXVII and XXVIII, CCXVI and CCXXXIII, and CCXXXIV are classified together, the substitution pattern of the core ring is different. Groups X and XXVII have substituents Q¹ and Q² in the 3-position but Groups XI and XXVIII has the same substituents in the 4-position. Thus, these are patentably distinct ring for a reference against Group X would not be a reference against group XI.

Should Applicants elect group XVII, XXXIV, CCXXIII, or CCXL then additional restriction may be required and a requirement to elect a specific disclosed species may be made.

Should Applicants traverse the restriction requirement on the grounds that the different core rings are not patentably distinguishable, Applicants should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence may be used in a rejection under 35 USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

4. Inventions I-XXVII and XXXV-CCVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case for example, other drugs such as nitroglycerine can treat angina pectoris, a disease listed in claim 53. Applicants admit that their products of claim 1 have uses for treating at least sixteen distinct diseases. Thus, both prongs of the test are met.

Should Applicants elect any one of the Groups XXXV-CCVI, then a specific disease and specific core should be specified for examination.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting

rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

6. Inventions I-XXVII and CCVII-CCXXIII, and CCXXIV-CCXL are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as synthons for simpler or different final products and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Various triplets of groups selected from Groups I-XXVII, CCVII-CCXXIII, and CCXXIV-CCXL will have identical classifications. However, Applicants use different formulas to represent the claimed compounds in each of these triplets.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply

does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

10. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

11. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Binta Robinson whose telephone number is

Art Unit: 1625

TCM ⁹²
(571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact Thomas C McKenzie, Ph. D., SPE of Art Unit 1625, at (571)-272-0670.

TCMcK/me


Thomas C. McKenzie, Ph.D.
SPE
Art Unit 1625